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10/798,613	03/11/2004	Timothy G. Laske	P11433.00	6204

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EXAMINER	
DINGA, ROLAND	
ART UNIT	**PAPER NUMBER**
3709	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/798,613	LASKE ET AL.	
	Examiner	Art Unit	
	ROLAND DINGA	3709	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/14/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claim 11-16, drawn to a method of treating a cardiac condition, classified in class 607, subclass 14.

   II. Claim 1-10,17-22, drawn to a system for delivering a biologic agent and providing an implantable medical device for cardiac function, classified in class 607, subclass 3.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the system disclosed can be applied to monitor and treat various other physiological organs such as the brain, pancreas, liver, stomach venous system, nervous system, and the spine.

3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Daniel G. Chapik on Tuesday, July 17, 2007, a provisional election was made with traverse to prosecute the invention of group 2, claim1-10 and claim 17-22. Applicant in replying to this Office action must make affirmation of this election. Claim 11-16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Claim 11-16 withdrawn from further consideration pursuant to 37 CFR 1.42(b), as being drawn to a nonelected method of treating a cardiac condition, classified in class 607,subclass 14, there being no allowable generic or linking claim. Applicant's representative (Daniel G. Chapik) timely traversed the restriction (election) requiring in the reply called in on 07/17/2007.

6. With further review, the redrawn group I (claims 11-16), were later reinstated for review of the application due to common practice in the particular Art Unit. Methods were determine to be closely related to the apparatus claimed and thus, showed no burden for the examiner when considering both parts.

Specification

7. The disclosure is objected to because of the following informalities: The recitation " other therapeutic solutions can be delivered in various does (paragraph [0033] line 8-9) is grammatically awkward. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. **Claims 15,14, and 18** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 15, the applicant limits the method of accessing the lumen through the implantable medical device by claiming a specific measure of " exposing a portion of the IMD post implant." The claim as presently recited, fails to indicate what the IMD is going to be exposed to. The claim as written can be interpreted in multiple fashions including exposing to air, exposing to the biologic, or exposure to a syringe (as claimed in applicant's claim 16). For the purpose of examining this limitation, it is assumed that the IMD is exposed to the syringe.

In claims 14 and 18, there is no structure in applicant's disclosure that shows the "means for delivering supplemental material." The examiner reads this claims as a 112, 6th paragraph ("....claim shall be construed to cover the corresponding structure...described in the specification...."). For the purpose of examining this limitation, it is assumed that ... "means for delivering supplemental material" .. is the delivery of second dose of drug.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-2,3-4, 6-8, and 11,13 are **rejected under 35 U.S.C. 102(b)** as being anticipated by Altman et al U.S.Pat.No.6086582.

Regarding **claim 1,** Altman et al discloses an implantable device that deliver a biological agent (Col 3. line 66-67 Col 4 lines 1-2). An implantable medical device (Co.5, lines 29-32) for monitoring cardiac function (col 6, line 4-8). Altman et al discloses a reservoir "16" for containing and dispensing a solution containing a biologic (col 5, line 46-51), a lumen 12 couple to the reservoir and positionable within the lead (catheter 14) to allow the solution to be delivered to the targeted area (See fig 1a).

Regarding **claim 2,** Altman et al discloses a mapping system for detecting catheter (lead) position in the heart, and also discloses that the catheter 14 has a single electrode for sensing the electrical potential of the implanted site (Col.6, line 19-21; Col 8, line 19- 25).

Regarding **claim 3-4**, Altman et al discloses IMD that monitor the effect of the biologic agent and also provide a device-based therapy ("electrical therapy

device") when the biologic agent is unable to terminate arrhythmic (Col 15,line 12 - 22).

With respect to **claim 6,** Altman et al discloses delivery of a second dosage ("taken to be the supplementary material") at selected area of heart tissue (Col 15, lines 15-23) and (Col.4, lines 30-32).

With respect to **claim 7-8** Altman et al discloses an embodiment with an implantable reservoir 16 (Col 5,line 46-48). And the implantable reservoir 304 is implant within an implant catheter (see fig 3a).

Regarding **claim 11,** Altman et al discloses an implantable device that deliver a biological agent (Col 3. line 66-67 Col 4 lines 1-2). An implantable medical device (Co.5, lines 29-32) for monitoring cardiac function (col 6, line 4-8). Altman et al discloses a reservoir "16" for containing and dispensing a solution containing a biologic (col 5, line 46-51), a lumen 12 couple to the reservoir and positionable within the lead (catheter 14) to allow the solution to be delivered to the targeted area (See fig 1a). Altman et al also discloses a fixation (24) helix ("taken to be the anchor") at the tip of the catheter (see fig 1a) and also disclose electrical therapy device (" taken to be the device based therapy") as the device senses cardiac activity (Col.15,lines 12-23)

Claim 13, Altman discloses terminating the supply of biologic agent from the reservoir (Col.6, lines 11-12) in responsive to sensing a predetermine activity of the heart (Col. 6, lines 12-13).

11. **Claims 17 and 19** are rejected under 35 U.S.C. 102(b) as being anticipated by Kieval U.S.Pat.No.6178349.

Regarding **claim 17**, Kieval discloses implantable medical device IMD (see Fig 1, element 20) for delivery of biologic agent at a targeted anatomical position (Col.3, line 19-20). Monitoring of the physiological performance of the anatomical position (Col.9, line 41-43) and selectively provides device base therapy of the monitored physiological performance (Col.9, line 41-67;Col.10, lines 37-44).

Regarding **claim 19,** Kieval discloses means for delivery include an implantable reservoir 260 (See Fig.8).

12. **Claims 1,6 -11,14 -16** are rejected under **35 U.S.C. 102(e)** as being anticipated by Thompson, US Pub. No 2002/0111601.

With respect to **claims 1 and 11**, Thompson discloses IMD and a method of usage that monitors cardiac performance and controllably releases a biologically active agent to a target area from a reservoir as needed. The IMD monitor cardiac function (paragraph [0043] lines 11-12;figure 2). The prior art discloses an include reservoir for containing and dispensing a biological solution (paragraph [0027] line 5-8). A lead that is couple coupled to the IMD and positional at a target and that can also transit signals indicative of cardiac function. The embodiment of IMD2 shown in Fig 1 is coupled to two leads 62 and 64 implanted within a patient's right ventricle 66 and within the coronary sinus 68, respectively. Leads 62 and 64 may carry one or more sensors to provide an indication of the performance of the heart 4 (paragraph [0039] lines 6-11,figure1).

Also, tip electrode 72 and ring electrode 74 to delivery pacing pulses and to sense electrical activity within the patient's heart (paragraph [0040] lines 1-3,figure1). From figure 1 and 2, following leads 64 and 84, respectively, one would see that attached to the end of the lead are anchors positioned to hold the leads in position within the heart. The electrodes 72 and 86, as depicted in figure 1 and 2 respectively, are located at the specific targeted area within the heart's chamber. Thompson also discloses a drug delivery system in which comprises IMD capable of monitoring various physiological parameters using sensors (paragraph [0042] lines 11-12). The prior art IMD discloses an internal lumen within a catheter to dispense biologic solution (paragraph [0009] line 6-12). Thompson also discloses using electrical stimulation (" taken to be device ") therapy based on one or more biological signals ("cardiac performance") provided by the biological sensors (paragraph [0012], lines 4-7).

Regarding **claims 7-9**, Thompson discloses an implantable reservoir "213" (see Fig.5) that is also implantable within a IMD (paragraph [0009]. Line 6 - 8). Thompson also discloses a access port for fluid communication with the reservoir for permitting an introduction of material to the reservoir (paragraph [0009]. line 9 - 11,paragragraph [0053]. Line 4 - 7).

Regarding **claim 10**, Thompson discloses IMD systems that are in widespread use to provide site-specific and /or sustained delivery of beneficial agent (background: page 1 paragraph [0003] lines 3-4). Also, Thompson discloses IMD

2 that include a port for receiving a syringe. The syringe may be inserted through subcutaneous tissue into the port to refill reservoir (paragraph [0054]. Line 1 - 6). Regarding **claims 14-16**, Thompson discloses a method where after the biologic has been deposited within the reservoir, it is delivered to the implanted lumen "392" for release at the specified target area (paragraph [0086] line 1-4, Fig 10). The lumen, therefore, is accessible post implantation, and it dispenses the supplemental material housed in the reservoir 213. Thompson discloses a method for accessing the lumen via a syringe through a port of the IMD: " storage reservoir 213 coupled to the infusion pump may be refillable. For example, IMD2 mat include a port for receiving a syringe" (paragraph [0054]. Line 2-3, Fig 1). From (fig 1 and 6) it is shown that the IMD is in fluid communication with the lumen 250 (fig 4) that is located inside the connected catheter and extending through to the electrode 120 (fig 6). Since the language in applicant's claim 15 is taken to be to be embraced by IMD having exposure to the syringe, it reads on Thompson.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. **Claims 5 and 12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Altman et al as applied to claim 3 and claim 11 in number paragraph 10. Altman et al teaches ablating cardiac tissue at a targeted area but fail to teach ablating the target cardiac tissue when the efficacy is below a predetermined threshold after a predetermine period of time. However, It would have been obvious to one skill in the art to ablate the cardiac tissue after a predetermine period of time if the drug therapy fails.

15. **Claims 18 and 20 –21** are rejected under 35 U.S.C. 103(a) as being unpatentable over kieval as applied to claim 17, above, and further in view of Altman et al.

Regarding **claim 18,** Kieval does not teach delivery of supplemental material to the selection position of the heart. Altman teaches delivery of a second dosage to the specific site (Col.15, line 20). However, it would have been obvious to one skill in the art to include a supplemental drug means if the arrhythmia does not terminate (Col.15, line 19).

Regarding **claim 20**, Kieval does not explicitly teach the limitations of the rejected claim 20. However, Altman teaches terminating the supply of biologic agent from the reservoir (Col.6, lines 11-12) It would have been obvious to one skill in the art by the time the invention was made to modify the system of Kieval to stop the delivery of drug in responsive to sensing a predetermine activity of the heart (Col. 6, lines 12-13).

Regarding **claim 21**, Kieval teaches about a drug delivery implantable medical device IMD, but does not teach terminating the drug delivery by ablation. Altman on the other hand teaches about stopping the drug delivery by ablation technique. It would have been obvious to one skill in the art to terminate the drug delivery Kieval by the use ablation taught by Atlman et al because it destroy the cell at the targeted area (Col 2.line 30 - 63)

16. **Claim 22** is rejected under 35 U.S.C. 103(a) as being unpatentable over Kieval as applied to claim 17 in paragraph 11, and further in view of Shapland US Pat. No. 5042497.

Kieval teaches all the limitations of claim 17, but fail to teach the use of an overdrive pacing regardless of the monitor physiological performance. However, Shapland teaches about an implantable cardiac device that uses an overdrive pacing (Abstract. Line 7-8). It would have been obvious to one skill in the art to include an overdrive pacing disclose by Shapland to the implantable medical device of Kieval, because overdrive pacing suppresses premature ventricular contraction PVC (Col.3, line 25-29).

conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROLAND DINGA whose telephone number is 571 270 3644. The examiner can normally be reached on Monday through Friday from 8:30am to 5:00pm EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SAM YAO can be reached on 571 272 1224. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RD
09/14/07

Roland Dinga
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